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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DREWES et al.
Title: METHODS AND DEVICES FOR
MASS TRANSPORT ASSISTED
OPTICAL ASSAYS
Appl. No.: 09/675,518
Filing Date: September 19, 2000
Examiner: Forman, Betty J.
Art Unit: 1634

CERTIFICATE OF MAILING	
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RESPONSE TO OFFICE ACTION

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to Office Action mailed on April 10, 2002 ("Paper No. 8"), please enter the following amendments and consider the following remarks.

AMENDMENTS

In the specification

Please cancel paragraph 2, lines 9-11, and insert the following paragraph before the subtitle Background of the Invention on line 4. Marked-up and clean specification pages are provided herewith as Appendices A and B, respectively.

B₁ -- The present invention is a continuation of U.S. application serial no. 08/950,963, filed October 15, 1997, which is a continuation-in-part of U.S. application serial no. 08/742,255, filed October 31, 1996, each of which hereby is incorporated by reference. --

In the claims

Please replace claims 51, 53, 54, 57, 67, 69, 70, and 73 with the following amended claims. A mark-up version of the amended claims, indicating the changes, are provided herewith as Appendix C.

B₂ 51. (Amended) A support comprising a surface on which an assay for an analyte of interest can be performed, comprising:

an attachment layer comprising diamond-like carbon on the support surface, wherein the attachment layer is adapted for capture of the analyte of interest for detection in the assay by binding the analyte directly to the diamond-like carbon.

B₃ 53. (Amended) A support according to claim 51, wherein a degree of hydrophobicity of the attachment layer results from a preselected sp^2 and sp^3 character of the diamond-like carbon.

54. (Amended) A support according to claim 51, wherein the diamond-like carbon is an antireflective layer.

B₄ 57. (Amended) A support according to claim 51, wherein the support provides laminar flow through or across the support.

67. (Amended) A support comprising a surface on which an optical assay for an analyte of interest can be performed, comprising:

B₅ an attachment layer comprising a layer of diamond-like carbon of between about 50 Å to about 500 Å in thickness on the support surface, wherein said attachment layer comprises a capture molecule bound to said diamond-like carbon for specific capture of said analyte by binding said analyte to said capture molecule.

B₆ 69. (Amended) A support according to claim 67, wherein a degree of hydrophobicity of the attachment layer results from a preselected sp^2 and sp^3 character of the diamond-like carbon.

70. (Amended) A support according to claim 67, wherein said diamond-like carbon is an antireflective layer.

B₇ 73. (Amended) A support according to claim 67, wherein said support provides laminar flow through or across said support.

REMARKS

The instant invention relates in part to supports on which an assay for one or more analytes can be performed. In particular, the claimed invention relates to supports that are configured to capture analytes on a surface for detection, preferably by optical assay methods, through the use of an attachment layer comprising diamond-like carbon.

Claims 51-91 are pending in the instant application. Claims 51-82 are under examination, with claims 83-91 being withdrawn from consideration by the Examiner. Applicants have amended claims 51, 53, 54, 57, 67, 69, 70 and 73 herein. The amended claims are fully supported by the specification, and do not introduce new matter or require a new search. The amendments simply clarify the claimed invention using preferred terminology, and are not intended to further limit the claim, and should not be taken to do so.

Notwithstanding the foregoing, Applicants expressly reserve the right to pursue subject matter no longer claimed in the instant application in one or more applications which may claim priority hereto. Applicants respectfully request reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non-Art Related Remarks

Priority:

Applicants respectfully submit that the specification has been amended herein to reflect the appropriate priority claim.

35 U.S.C. §112, 2nd paragraph

In an effort to advance prosecution, Applicants have amended claims 53, 54, 57, 67, 69, 70 and 73 according to the Examiner's suggestions, thus rendering the rejection moot.

Art Related Remarks

35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 51, 52, 58-63, 66-68, 74-79 and 82 under 35 U.S.C. § 102(b) as allegedly being anticipated by Vadgama *et al.*, WO 93/24828, published 9 December 1993.

In order to anticipate a claim, a single prior art publication must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teachings of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP §2131.

The rejected claims relate to an assay support comprising an attachment layer comprising diamond-like carbon ("DLC"), in which the attachment layer is adapted to directly bind an analyte of interest to the DLC for detection in an assay (*e.g.*, claim 51) or in which the attachment layer comprises a capture molecule bound to the DLC (*e.g.*, claim 67). It is respectfully submitted that the Vadgama *et al.* publication does not teach or suggest an assay support having an attachment layer as described in the instant claims.

Rather, the Vadgama *et al.* publication describes a method that uses DLC as a shield to prevent biofouling of an electrode surface. Vadgama *et al.*, page According to the Vadgama *et al.* publication, such a covering DLC layer should be selected for "a high degree of inertness" (Vadgama *et al.*, page 8, lines 21-23) -- that is, so that the analyte is not bound -- and therefore such a DLC layer is not adapted for capture of the analyte of interest for detection, as required by the instant claims.

This "inertness" is a required feature of the devices disclosed by the Vadgama *et al.* publication, as the DLC "biocompatible shield" (Vadgama *et al.*, page 5, lines 25-30) is not used for analyte detection, a function that is provided by an internal electrode assembly. Vadgama *et al.*, page 1, lines 1-22. Indeed, should the DLC "biocompatible shield" actually bind the analyte of interest, the assay devices disclosed by the Vadgama *et al.* publication could not function, as

the internal electrode assembly would not be exposed to an analyte level representative of the sample.

Thus, rather than disclosing the invention described in the rejected claims, the Vadgama *et al.* publication discloses the use of a DLC layer providing precisely the opposite characteristics of the claimed invention. The Examiner's contention that "the properties of the claimed diamond-like carbon are necessarily present in the diamond-like carbon of Vadgama *et al.*" (Paper No. 8, page 11) ignores the fact that DLC is not a single "chemical composition" having a single set of properties any more than carbon itself has a single set of properties. As such, DLC can have numerous characteristics, *e.g.*, varying hydrophobicity, thickness, hardness, *etc.*, that can provide properties akin to diamond, akin to graphite, or akin to some intermediate form of carbon. Moreover the Examiner's contention is at odds with the fact that the Vadgama *et al.* publication provides DLC that is "inert" while the present application provides DLC that is adapted to acting as an attachment layer.

The instant claims refer to a substrate comprising an attachment layer comprising DLC, a structural component that is lacking in the devices disclosed in the Vadgama *et al.* publication. In view of this difference between the claimed invention and the cited publication, Applicants respectfully request that the Examiner cite objective evidence for the assertion that the DLC of the Vadgama *et al.* publication and the attachment layer of the instant claims necessarily have identical chemical structures and properties. *See, e.g.*, MPEP § 2112 (to establish inherency, the Examiner must provide objective evidence that the missing descriptive matter is necessarily present in the cited publication).

Because the Vadgama *et al.* publication does not teach each and every element set forth in the claims, no *prima facie* case of anticipation has been established. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 53, 54, 69 and 70 under 35 U.S.C. §103(a), as allegedly being unpatentable over Vadgama *et al.* in view of Yu, US Patent No.

5,273,788 ("the '788 patent"); claims 55-57 and 71-73 as allegedly being unpatentable over Vadgama *et al.* in view of Kobashi, US Patent No. 5,777,372 ("The '372 patent"); and claims 64, 65, 80 and 81 as allegedly being unpatentable over Vadgama *et al.* in view of Choi *et al.*, US Patent No. 5,883,769 ("The '769 patent").

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited publications or in knowledge available to the ordinarily skilled artisan, to modify or combine the publications; there must be a reasonable expectation of success in combining the publications; and the publications must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) See also MPEP §2143.

As discussed above, the Vadgama *et al.* publication does not disclose a substrate that comprises an attachment layer comprising DLC that is adapted to directly bind an analyte of interest to the DLC for detection in an assay, or in which the attachment layer comprises a capture molecule bound to the DLC. Moreover, the Vadgama *et al.* publication does not suggest such an attachment layer, as the Vadgama *et al.* publication specifically discloses that DLC layer should be selected for "a high degree of inertness" so that the analyte is not bound. Thus, the Vadgama *et al.* publication teaches away from providing the attachment layer of the instant claims.

This flaw in the Examiner's purported *prima facie* case is not cured by combining the Vadgama *et al.* publication with any of the secondary references cited by the Examiner. For example, with regard to the '788 patent, this publication is cited for allegedly disclosing "variations in sp2 and sp3 characteristics" of DLC and using DLC as an antireflective layer. Paper No. 8, page 9. The '788 patent, however, is silent as to the possible use of DLC as an attachment layer on an assay support.

Moreover, the Examiner has provided no indication whatsoever as to why the skilled artisan would be motivated to vary the sp2 and sp3 characteristics of the DLC layer of the Vadgama *et al.* publication as allegedly disclosed in the '788 patent. See, e.g., *In re Kotzab*, 55

USPQ2d 1313, 1317 (Fed. Cir. 2000) (in support of an obviousness rejection, "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed" in order to support an obviousness rejection) (emphasis added).

With regard to the '372 patent, the publication is cited for allegedly disclosing "an optical functional layer between the support and the attachment layer." But, like the Vadgama *et al.* publication, the '372 patent does not teach or suggest an attachment layer comprising DLC, or a motivation for providing such a layer.

Moreover, the Examiner's assertion that the '372 patent discloses laminar flow as recited in instant claims 57 and 73, or an optically functional layer that undergoes a change in optical thickness that attenuates one or more wavelengths of light as recited in instant claims 71 and 72, is without support. The section of the '372 patent cited by the Examiner (column 10, lines 50-55) disclose a semiconductor optical biosensor that provides an electrical change, and not a substrate that provides a change in optical properties, upon analyte binding. As noted in the instant specification, the provision of laminar flow is not necessarily provided simply by having flow across or through a surface. *See, e.g.*, specification, page 3, lines 6-20. Similarly, the provision of an optically functional layer is nor provided simply by placing DLC on a surface. *See, e.g.*, specification, page 10, lines 4-23.

With regard to the '769 patent, the Examiner refers to a publication that discloses heads for use in a videocassette recorder. Applicants respectfully submit that this is nonanalogous art which the skilled artisan would not consider to be pertinent to the field of assay devices. As such, the Examiner may not rely on this publication in support of the present rejection. *See*, MPEP §2141.01(a).

Moreover, the Examiner has provided no indication as to why the skilled artisan would have any motivation to modify the hardness or refractive index of the DLC layers. Once again, the Examiner's contention that DLC has a particular hardness or refractive index is based on the allegation "the properties of the claimed diamond-like carbon are necessarily present in the

diamond-like carbon of Vadgama *et al.*" (Paper No. 8, page 15). This ignores the fact that DLC is not a single "chemical composition" having a single set of properties any more than carbon itself has a single set of properties. As such, DLC can have numerous characteristics, *e.g.*, varying hydrophobicity, thickness, hardness, *etc.*, that that can provide properties akin to diamond, akin to graphite, or akin to some intermediate form of carbon. Applicants respectfully request that the Examiner cite objective evidence for the assertion that the DLC of the Vadgama *et al.* publication and that of the instant claims have the recited hardness and refractive index properties.

Therefore, because the cited references, alone or in combination, fail to teach or suggest all of the limitations set forth in the instant claims, and because nothing in the Examiner's alleged *prima facie* case provides any motivation to modify the devices of the cited references to provide the instantly claimed invention, Applicants respectfully request that the rejections under 35 U.S.C. §103 be reconsidered and withdrawn.

Double Patenting

The Examiner has provisionally rejected claims 51-82 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7, 11, 23-34 and 38-50 of copending U.S. Application No. 08/950,963. Applicants respectfully submit that, because the instant claims are in allowable form, the provisional double patenting rejection is the only remaining rejection in the instant application. As such, the examiner should withdraw the rejection and permit the claims to issue. *See, e.g.*, MPEP 804(I)(B).

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Date July 18, 2002

FOLEY & LARDNER
P.O. Box 80278
San Diego, California 92138-0278
Telephone: (858) 847-6721
Facsimile: (858) 792-6773

Respectfully submitted,

By Michael A. Whittaker

Michael A. Whittaker
Attorney for Applicant
Registration No. 46,230



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Appendix A: Marked-up specification page, indicating amendments. Material to be added is indicated by double underline, and material to be deleted is indicated by strikethrough.

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